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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,939	04/12/2004	Tae H. Ji	028750-229	2139

21839 7590 08/23/2005

BUCHANAN INGERSOLL PC
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POST OFFICE BOX 1404
ALEXANDRIA, VA 22313-1404

EXAMINER	
BORGEEST, CHRISTINA M	

ART UNIT	PAPER NUMBER
1649	

DATE MAILED: 08/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/821,939	JI ET AL.	
	Examiner	Art Unit	
	Christina Borgeest	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *April 12, 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-53* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

Restriction to one of the following Groups is required under 35 U.S.C. 121:

I. Claims 1-5 (in part), 7, 8-11 (in part), 14, 15, 28 (in part) and 29 (in part), drawn to a method of administering to a female subject an agent that modulates CG activity or CG interaction with exoloop 1, exoloop 2 or exoloop 3 of the LHR, classification dependent on structure of recited "agent".

II. Claims 1-5 (in part), 6, 8-11 (in part), 28 (in part) and 29 (in part), drawn to a method of administering to a male subject an agent that modulates CG activity or CG interaction with exoloop 1, exoloop 2 or exoloop 3 of the LHR, classification dependent on structure of recited "agent".

III. Claims 16-17 (in part) and 18, drawn to a method of contraception in a female subject comprising administering an agent that modulates CG or CG interaction with exoloop 1, exoloop 2 or exoloop 3 of the LHR, classification dependent on structure of recited "agent".

IV. Claims 16-17 (in part) and 19, drawn to a method of contraception in a male subject comprising administering an agent that modulates CG or CG interaction with exoloop 1, exoloop 2 or exoloop 3 of the LHR, classification dependent on structure of recited "agent".

V. Claim 20, drawn to a method of promoting fertility in a subject comprising administering an amount of agent effective at stimulating fertility wherein

the agent stimulates CG activity or CG interaction with exoloop 1, exoloop 2 or exoloop 3 of the LHR, classification dependent on structure of recited "agent".

VI. Claim 21, drawn to a method of screening for compounds that modulate the CG/LHR interaction comprising exposing CG to an agent, classification dependent on structure of recited "agent".

VII. Claims 22-26, in part drawn to a composition and a pharmaceutical excipient that modulates exoloop 1, exoloop 2 or exoloop 3 of the LHR, classification dependent on structure of recited "agent".

VIII. Claim 27, drawn to a composition comprising an antibody that binds to CG and prevents CG from interacting with the exoloop 1, exoloop 2 or exoloop 3 of LHR, classified in class 424, subclass 130.1.

IX. Claim 30, drawn to a method of identifying binding partners for CG comprising exposing the protein to a potential binding partner and determining if an exoloop 1, exoloop 2 or exoloop 3 domain of the potential binding partner binds to CG, classification dependent on structure of recited "partner".

X. Claims 31-36 (in part), 37, 38 (in part) and 52 (in part), drawn to a method of treating a gonadotropin hormone related disease in a male subject comprising administering an agent which modulates FSH activity or FSH interaction with FSHR, classification dependent on structure of recited "agent".

XI. Claims 31-36 (in part), 39, 40, 51 (in part) and 52 (in part), drawn to a method of treating a gonadotropin hormone related disease in a female subject comprising administering an agent which modulates FSH activity or FSH interaction with exoloop 1, exoloop 2 or exoloop 3 of the FSHR, classification dependent on structure of recited "agent".

XII. Claims 41 and 42, drawn to a method of contraception in a subject comprising administering an agent that modulates FSH activity or FSH interaction with exoloop 1, exoloop 2 or exoloop 3 of the FSHR, classification dependent on structure of recited "agent".

XIII. Claim 43, drawn to a method of promoting fertility in a subject comprising administering to a subject an amount of an agent effective at stimulating fertility, wherein the agent stimulates FSH activity or FSH interaction with exoloop 1, exoloop 2 or exoloop 3 of the FSHR, classification dependent on structure of recited "agent".

XIV. Claim 44, drawn to a method for screening compounds which modulate the interaction FSH/FSHR interaction comprising exposing FSH to an agent, classification dependent on structure of recited "agent".

XV. Claims 45-49, drawn to compounds and compositions that are FSHR modulating agents, classification dependent on structure of recited "agent".

XVI. Claim 50, drawn to a composition comprising an antibody capable of modulating FSH activity by preventing interaction of FSH with the exoloop

1, exoloop 2 or exoloop 3 domain of the FSHR, classified in class 424, subclass 130.1.

XVII. Claim 53, drawn to a method of identifying binding partners for FSH comprising the steps of exposing the protein to a potential binding partner; and determining if the exoloop 1, exoloop 2 or exoloop 3 domain of the potential binding partner binds to FSH, classification dependent on structure of recited "partner".

Groups I-VI, IX-XIV and XVII are unrelated methods. Groups are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP 806.04, MPEP 808.01). Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions (reasons to follow in this paragraph). Furthermore, although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions (reasons to follow in this paragraph). For instance, Groups I-II are drawn to methods of administering an agent that modulates CG activity, whereas Groups III-IV and XII are drawn to methods of contraception, comprising administering an agent that modulates gonadotropin hormone/gonadotropin hormone receptor interaction. Groups V and XIII are drawn to methods of promoting fertility,

comprising administering an agent that modulates gonadotropin hormone/gonadotropin hormone receptor, and differ from Groups I-II, which are drawn to methods of administering an agent that modulates CG activity. Groups VI and XIV and are drawn to methods of screening for compounds that modulate gonadotropin hormone/gonadotropin hormone receptor interaction, and differ from Groups I-II are drawn to methods of administering an agent that modulates CG activity. Groups X-XI are drawn to methods of administering an agent that modulates FSH activity for the treatment of gonadotropin hormone related disease, and differ from Groups I-II, which are drawn to methods of administering an agent that modulates CG activity. Groups IX and XVII are drawn to methods of identifying binding partners for gonadotropin hormones, and differ from Groups I-II, which are drawn to methods of administering an agent that modulates CG activity. Groups III-IV and XII are drawn to methods of contraception, comprising administering an agent that modulates gonadotropin hormone/gonadotropin hormone receptor interaction, and differ from Groups X-XI, which are drawn to methods of administering an agent that modulates FSH activity to treat gonadotropin hormone related disease. Furthermore, Groups III-IV and XII, which are drawn to methods of contraception, comprising administering an agent that modulates gonadotropin hormone/gonadotropin hormone receptor interaction, differ from Groups V and XIII, which are drawn to methods of promoting fertility, comprising administering an agent that modulates gonadotropin hormone/gonadotropin hormone receptor. Groups IX and XVII, which are drawn to methods of identifying binding partners for gonadotropin hormones differ from and differ from Groups III-IV and XII,

which are drawn to methods of contraception, comprising administering an agent that modulates gonadotropin hormone/gonadotropin hormone receptor interaction. Groups VI and XIV are drawn to methods of screening for compounds that modulate gonadotropin hormone/gonadotropin hormone receptor interaction, and differ from Groups III-IV and XII, which are drawn to methods of contraception, comprising administering an agent that modulates gonadotropin hormone/gonadotropin hormone receptor interaction. Groups V and XIII are drawn to methods of promoting fertility, comprising administering an agent that modulates gonadotropin hormone/gonadotropin hormone receptor and differ from Groups X-XI, which are drawn to methods of administering an agent that modulates FSH activity to treat gonadotropin hormone related disease. Groups VI and XIV are drawn to methods are drawn to methods of screening for compounds that modulate gonadotropin hormone/gonadotropin hormone receptor interaction, and differ from Groups X-XI, which are drawn to methods of administering an agent that modulates FSH activity to treat gonadotropin hormone related disease. Groups IX and XVII are drawn to methods are drawn to methods of identifying binding partners for gonadotropin hormones, and differ from Groups X-XI, which are drawn to methods of administering an agent that modulates FSH activity to treat gonadotropin hormone related disease. Groups V and XIII are drawn to methods of promoting fertility, comprising administering an agent that modulates gonadotropin hormone/gonadotropin hormone receptor, and differ from Groups VI and XIV, which are drawn to methods of screening for compounds that modulate gonadotropin hormone/gonadotropin hormone receptor interaction. Groups IX and XVII are drawn to

methods of identifying binding partners for gonadotropin hormones, and differ from Groups V and XIII, which are drawn to methods of promoting fertility, comprising administering an agent that modulates gonadotropin hormone/gonadotropin hormone receptor. Groups IX and XVII are drawn to methods are drawn to methods of identifying binding partners for gonadotropin hormones, and differ from VI and XIV, which are drawn to methods of screening for compounds that modulate gonadotropin hormone/gonadotropin hormone receptor interaction.

In the instant case, classification is dependent on the structure of recited "agents", "partners" or "compounds", the Groups are directed to methods that recite structurally and functionally distinct elements, are not required one for the other, and/or achieve different goals. Therefore, a search and examination of all methods in one patent application would result in an undue burden, since the searches for the methods are not co-extensive, the classification is different, and/or the subject matter is divergent. Furthermore, the distinct steps and products require separate and distinct searches. For these reasons, restriction for examination purposes as indicated is proper.

Groups I and II have different patient populations. Although both are drawn to a method of administering an agent that modulates a CG activity or CG interaction with exoloop 1, exoloop 2 or exoloop 3 of the LHR, classification dependent on structure of recited "agent", Group I is drawn to a method for administering an agent to females whereas Group II is drawn to a method of administering an agent to males. Because these Groups have distinct patient populations, the search required for Group I is not

the same as that required for Group II, restriction for examination purposes as indicated is proper.

Groups III and IV have different patient populations. Although both are drawn to a method of contraception comprising administering an agent that modulates CG or CG interaction with exoloop 1, exoloop 2 or exoloop 3 of the LHR, classification dependent on structure of recited "agent", Group III is drawn to a method of contraception in females and Group IV is drawn to a method of contraception in males. Because these Groups have distinct patient populations, the search required for Group III is not the same as that required for Group IV, restriction for examination purposes as indicated is proper.

Groups III and XII utilize different mechanisms. Although both are drawn to a method of contraception, Group III is drawn to a method comprising administration of an agent that modulates CG or CG/LHR interaction and Group XII is drawn to a method comprising administering an agent that modulates FSH or FSH/FSHR interaction, classification dependent upon the structure of recited "agent". Because these Groups have distinct mechanisms, the search required for Group III is not the same as that required for Group XII.

Groups IV and XII utilize different mechanism. Although both are drawn to a method of contraception, Group IV is drawn to a method comprising administration of an agent that modulates CG or CG/LHR interaction and Group XII is drawn to a method comprising administering an agent that modulates FSH or FSH/FSHR interaction, classification dependent upon the structure of recited "agent". Because these Groups

have distinct mechanisms, the search required for Group IV is not the same as that required for Group XII.

Groups V and XIII utilize different mechanisms. Although both are both drawn to methods that promote fertility, Group V is drawn to a method of promoting fertility in a subject comprising administering an amount of agent effective at stimulating fertility wherein the agent stimulates CG activity or CG interaction with exoloop 1, exoloop 2 or exoloop 3 of the LHR and Group XIV is drawn to a method of stimulating fertility, wherein the agent stimulates FSH activity or FSH interaction with exoloop 1, exoloop 2 or exoloop 3 of the FSHR, classification dependent on structure of recited "agent". Because the Groups have distinct mechanisms, the search required for Group V is not the same as that required for Group XIV, restriction for examination purposes as indicated is proper.

Groups VII and XV have different molecular targets. Although both are drawn to compounds and/or compositions that modulate glycoprotein hormone receptors, classification dependent on structure of recited "compounds" and or "compositions", Group VII is drawn those compounds that modulate the LHR, and Group XV is drawn to those compounds or compositions that modulate the FSHR.

Groups VIII and XVI are antibodies with different molecular targets. Although both are drawn to antibodies, Group VIII is drawn to an antibody that blocks CG/LHR interaction and Group XVI is drawn to an antibody that blocks FSH/FSHR interaction, classification dependent on structure of recited "agent". Because the Groups have distinct molecular targets, the search required for Group VIII is not the

same as that required for Group XVI, restriction for examination purposes as indicated is proper.

Groups X and XI have different patient populations. Although both are drawn to methods of treating gonadotropin hormone related disease comprising administering an agent which modulates FSH activity or FSH interaction with FSHR, classification dependent on structure of recited "agent", Group X is drawn to a method of administering an agent to males and Group XII is drawn to a method of administering an agent to females. Because these Groups have distinct patient populations, the search required for Group X is not the same as that required for Group XI, restriction for examination purposes as indicated is proper.

Groups VI and XIV utilize different mechanisms. Groups VI and XIV are drawn to methods for screening compounds that interact with different receptors; Group VI is drawn to a method of screening for compounds that modulate the CG/LHR interaction comprising exposing CG to an agent, whereas Group XIV is drawn to a method for screening compounds which modulate the FSH/FSHR interaction comprising exposing FSH to an agent, classification dependent on structure of recited "agent". Because these Groups utilize distinct mechanisms, the search required for Group VI is not the same as that required for Group XIV, restriction for examination purposes as indicated is proper.

Groups IX and XVII utilize different mechanisms. Although both are drawn to methods for identifying binding partners for glycoprotein hormones comprising exposing the protein to a potential binding partner, classification dependent on structure of recited

"partner", Group IX is drawn to CG, whereas Group XVII is drawn to FSH. Because these Groups utilize different mechanisms, the search required for Group IX is not the same as that required for Group XVII, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention. There are two groups of species, stimulation of hormones, tissues and cells, and diseases:

PART I: STIMULATION OF HORMONES, TISSUES, CELLS

I-a)stimulation of progesterone, androgen and estrogen stimulation

I-b)stimulation of development of the male gonads

I-c)stimulation of development of the female gonads, follicles, maturation of oocytes

I-d)stimulation of development of the placenta

I-e)stimulation of development of the sperm

I-f) growth of cells/tissue

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-28, 30-51 and 53 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim

is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

This application contains claims directed to the following patentably distinct species of the claimed invention:

PART II: DISEASES

II-a) male pseudohermaphroditism

II-b) microphallus

II-c) gynecomastia

II-d) bilaterial anorchia

II-e) absence of Leydig cells

II-f) crytpochroidsm

II-g) Noonan syndrome

II-h) myotonic dystrophy

II-i) delayed puberty

II-j) precocious puberty

II-k) acne

II-l) impotence

II-m) primary and secondary amenorrhea

II-n) endometriosis

II-o) uterine myoma

II-p) ovarian and mammary cystic diseases

II-q) breast cancer

II-r) gynecological cancers

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-12, 14-37, 39-53 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include

all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christina Borgeest whose telephone number is 571-272-4482. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christina Borgeest, Ph.D.
August 8, 2005

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER